

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

BAYER SCHERING PHARMA AG &
BAYER HEALTHCARE
PHARMACEUTICALS INC.,

Plaintiffs,

v.

LUPIN LIMITED and LUPIN
PHARMACEUTICALS, INC.,

Defendants.

Civil Case No. 2:10-cv-01166-GMN-RJJ

**JOINT PROPOSED PROTECTIVE
ORDER**

PROTECTIVE ORDER

WHEREAS, discovery in this action may involve the disclosure of certain documents, things, and information in the possession, custody or control of Plaintiffs Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. (collectively "Plaintiffs"), Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively "Defendants"), or other persons that constitute or contain trade secrets or other confidential research, development, or commercial information within the meaning of Rule 26(c)(7) of the Federal Rules of Civil Procedure ("Fed. R. Civ. P.");

WHEREAS, such confidential information must be protected in order to preserve the legitimate business interests of the parties or other persons;

WHEREAS Plaintiffs and Defendants have, through counsel, stipulated to the entry of this Protective Order for the purpose of advancing the progress of this case and to prevent unnecessary dissemination or disclosure of such confidential information;

IT IS HEREBY ORDERED that:

Definitions

Confidential Information

1. The term “Confidential Information” includes all non-public information that the designating party reasonably believes should be protected from public disclosure because such information includes:

- (a) proprietary licensing, distribution, design, redevelopment, research, test data, manufacturing, financial, pricing, technical, or trade secret nature;
- (b) privacy interests of individuals;
- (c) technical information, financial information (including internal sales figures, costs, pricing, profits and future sales projections) and proprietary information (including business plans, marketing plans, production capacity, launch information and customer lists);
- (d) information regarding the identity of and marketing information regarding customers, vendors, contractors, suppliers, and other non-parties with whom the parties do business;
- (e) clinical studies;
- (f) the New Drug Application and the Abbreviated New Drug Application at issue in this action except to the extent that information contained therein is public under the Freedom of Information Act;

- 1 (g) production information, including, but not limited to trade secrets
2 or confidential research, development, or commercial information;
3 (h) information submitted to FDA, or any other governmental agency,
4 that under applicable regulations is exempt from disclosure under
5 the Freedom of Information Act;
6 (i) information that a party obtained from another entity and which the
7 party is required to keep confidential pursuant to an agreement
8 entered into with such entity in the regular course of business;
9 (j) personnel compensation, evaluations, or other private employment
10 information; or
11 (k) confidential or proprietary information about affiliates, parents,
12 subsidiaries, or third parties with whom the Parties to this action
13 have had or have endeavored to have business relationships.
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15 Confidential Information shall apply to all information, documents, and things within the
16 scope of discovery in this action that are designated as containing or comprising
17 Confidential Information, including, without limitation, documents and things responsive
18 to requests for production of documents and things under Fed. R. Civ. P. 34; information
19 produced by other persons which the producing or designating party is under an
20 obligation to maintain in confidence; responses to written interrogatories under Fed. R.
21 Civ. P. Rule 33; responses to requests for admission under Fed. R. Civ. P. Rule 36 or
22 other discovery requests; testimony adduced at depositions upon oral examination or
23 upon written questions pursuant to Fed. R. Civ. P. Rules 30 and 31, hearings, or trial.
24 The information contained therein and all copies, abstracts, excerpts, analyses, or other
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1 writings that contain, reflect, reveal, suggest, or otherwise disclose such information shall
2 also be deemed Confidential Information. Information originally designated as
3 Confidential Information shall not retain that status after any ruling by the Court denying
4 such status to it.

5 **Foreign Confidential Information.**

6 2. Bayer Schering Pharma AG may designate as Confidential those
7 documents (hereafter referring to any data in electronic form or in paper form) containing
8 "personal data," within the sense of the German Federal Data Protection Act, the
9 confidentiality of which is protected under German law. Personal data consists of: any
10 and all data which concerns an identified person or a person who is identifiable with
11 recourse to additional information available to the data processor (e.g., reference to an
12 individual by his/her position within the company such as "Head of Finance" whose
13 identity results from other sources of information). In particular, this applies to the
14 following documents:
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- 16 (a) any correspondence (electronic or on paper) which identifies or
17 through recourse to other sources of information available to the
18 data processor allows identification of its author/sender and/or its
19 addressee/recipient, i.e., for example, all email correspondence,
20 letters and faxes (including transmission reports);
21
22 (b) any document such as memoranda, notes, and presentations if they
23 identify or allow identification of its author/sender and/or its
24 addressee/recipient through recourse to other information available
25 to the data processor;
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1 (c) minutes of internal or external meetings as far as they include
2 information about which individual(s) did or did not attend the
3 meeting; and

4 (d) personnel records and information.

5 3. The term “designating party” means the party or person designating
6 documents or information as Confidential Information under this Protective Order.

7 4. The term “receiving party” shall mean the party to whom Confidential
8 Information is disclosed.

9 5. Notwithstanding anything to the contrary herein, the description
10 Confidential Information shall apply to all that information so designated by the
11 designating party absent an order of the Court or subsequent written agreement of the
12 designating party providing otherwise.
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14 **Designation Of Confidential Information**

15 6. Each designating party who produces or discloses any material that it
16 believes contains or comprises Confidential Information shall so designate the same.

17 With respect to documents or copies provided by one party to the other, the designating
18 party shall mark the initial page and the page or pages on which any Confidential

19 Information appears with the legend “CONFIDENTIAL,” or a marking of like import.

20 Materials such as videotapes, audio tapes, and electronic media such as computer disks,
21 compact discs, or DVDs, which contain or include Confidential Information, shall be
22 designated by affixing the aforementioned legend on the package thereof. In lieu of

23 marking the original of a document which contains Confidential Information prior to
24 inspection, counsel for the producing party may orally or in writing designate documents

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1 or things being produced for inspection as containing Confidential Information, thereby
2 making them subject to this Protective Order; however, any copies of such documents
3 must be marked by the producing party in accordance with this Protective Order at the
4 time copies are provided to a receiving party.

5 7. If any Confidential Information is produced by a person other than the
6 parties to this Protective Order, such person shall be considered a "designating party"
7 within the meaning of that term as it is used in the context of this Protective Order, and
8 both parties to this Protective Order shall be treated as receiving parties. The parties
9 recognize that, during the course of this litigation, Confidential Information that
10 originated with a person other than a party and for which there exists an obligation of
11 confidentiality may be produced. Such information that the designating party believes
12 originated with such person, but is subject to a confidentiality obligation, may be
13 designated as Confidential Information and shall be subject to the restrictions on
14 disclosure specified in Paragraph 10.
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16 8. In the event a party or person producing information, through
17 inadvertence, produces or provides information without correctly designating it
18 Confidential Information as provided in this Protective Order, the producing party may
19 give written notice to the receiving party or parties that the document, thing, other
20 discovery information, response or testimony is Confidential Information and shall be
21 treated in accordance with the provisions of this Protective Order. The receiving party or
22 parties must treat such documents, things, information, responses, and testimony as
23 Confidential Information from the date such notice is received in accordance with the
24 provisions of this Protective Order. Upon receipt of such notice, and upon receipt of
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1 properly marked documents, things, information, responses, or testimony, the receiving
2 party shall return or destroy said unmarked or incorrectly marked documents, things,
3 information, responses, and testimony and not retain copies thereof. Upon notice to the
4 receiving party of such failure to designate, the receiving party shall reasonably cooperate
5 to correct any disclosure to maintain the confidentiality of the inadvertently disclosed
6 information, without prejudice.

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8 9. Inadvertent production of documents or information subject to the attorney
9 client privilege or work product immunity shall not constitute a waiver of such privilege.
10 After receiving notice from the producing party that documents or information subject to
11 the attorney client privilege or work product immunity have been inadvertently produced,
12 the receiving party shall not review, copy, or disseminate such documents or information.
13 The receiving party shall return such documents or information and all copies of such
14 documents or information to the producing party immediately. This return of such
15 inadvertently produced documents shall not constitute a waiver or otherwise preclude the
16 receiving party from challenging the propriety of the designation of such documents or
17 information as subject to the attorney-client privilege or attorney work product immunity.
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19 **Disclosure Of Confidential Information**

20 10. Except as provided elsewhere in this Protective Order, information
21 designated as Confidential Information may be disclosed only to the following
22 individuals:

- 23
24 (a) Outside attorneys for any party and stenographic, clerical, and
25 paralegal employees or independent contractors (e.g., contract
26 attorneys, photocopiers, translators, interpreters, etc.) of such
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1 attorneys. At present, such attorneys are those from the firms
2 Bartlit Beck Herman Palenchar & Scott LLP; Lewis and Roca
3 LLP; Leydig, Voit & Mayer, Ltd.; and Santoro, Driggs, Walch,
4 Kearney, Holley & Thompson, but this provision shall include
5 attorneys with other law firms provided their law firm has at least
6 one attorney that has entered an appearance and signed this
7 Protective Order;

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9 (b) Independent consultants or experts (and their staff) retained by the
10 attorneys for the parties either as technical consultants or expert
11 witnesses for the purposes of this litigation, as long as these
12 personnel comply with the procedure of Paragraph 18 herein;

13 (c) Each person or firm retained by Plaintiffs or Defendants for the
14 purpose of producing graphic or visual aids, as long as these
15 personnel comply with the procedure of Paragraph 18 herein;

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17 (d) The Court, Court personnel, and Official Court Reporters and
18 Videographers to the extent that Confidential Information is
19 disclosed at a deposition or Court session which such reporter is
20 transcribing or recording; and

21 (e) Three persons employed by or affiliated with Plaintiffs and three
22 persons employed by or affiliated with Defendants (“inside
23 counselors”), provided that such persons are not involved in patent
24 prosecution and are not primarily responsible for regulatory
25 matters concerning the Food and Drug Administration, and
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1 provided further that, before such persons receive any disclosure as
2 permitted under this Protective Order of Confidential Information,
3 each party shall disclose such person to the other party along with a
4 description of their job responsibilities and each such person shall
5 review and agree to be bound by the terms of this Protective Order
6 by signing the Declaration of Compliance. If the other party does
7 not object to the disclosure of Confidential Information to such
8 person within seven (7) business days, then such person may
9 review Confidential Information. Production sets of documents
10 containing Confidential Information shall be maintained at the
11 offices of outside attorneys only. To the extent Confidential
12 Information is provided to inside counselors at their offices, that
13 information shall be maintained in a secure fashion and shall not be
14 shared or disseminated.

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16 Plaintiffs and Defendants shall each have the right to substitute
17 new persons for existing inside counselors, provided that the
18 previous persons are no longer in the employ of or affiliated with
19 the respective party, provided that such new persons meet the
20 above criteria and the parties comply with the procedures set forth
21 in this paragraph, and provided further that at any time no more
22 than three inside counselors for Plaintiffs and no more than three
23 inside counselors for Defendants shall have access to information
24 designated by the opposing party as Confidential pursuant to this
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1 Protective Order. The foregoing lists in this Paragraph may be
2 expanded by mutual agreement in writing by counsel for Plaintiffs
3 and Defendants.
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5 **Use And Control Of Confidential Information**

6 11. Before an independent consultant or expert is afforded access to another
7 party's Confidential Information, the identity and current resume or curriculum vitae of
8 the expert shall be furnished to all parties. The resume or curriculum vitae may be
9 provided at any time after this Protective Order is signed by the parties. No material
10 designated Confidential Information shall be disclosed to such expert consultant until
11 after the expiration of a five (5) business day period commencing upon the receipt by
12 opposing counsel of the identity and current resume or curriculum vitae of the expert
13 ("Expert Notice"). If, within five (5) business days of receipt of an Expert Notice (the
14 date of receipt not counting as one of the five (5) days), any party objects, in writing and
15 with an explanation of the basis for the objection, to the proposed disclosure to the
16 expert, the parties shall then have three (3) additional business days after an objection is
17 raised to use good faith efforts to reach an agreement regarding the proposed disclosure
18 to the expert, during which period of time disclosure may not be made absent an
19 agreement. If an agreement cannot be reached, the party objecting to disclosure may
20 apply to the Court for relief within five (5) business days after it is determined that an
21 agreement cannot be reached. The burden shall be on the objecting party to show the
22 Court good cause why the disclosure should not be made. In the event an application is
23 made to the Court, however, the materials will continue to be treated as Confidential
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1 Information in accordance with this Protective Order during the time the Court considers
2 the application and will not be disclosed to the consultant or expert.

3 12. All information designated as Confidential Information pursuant to this
4 Protective Order and disclosed in this litigation shall be used by a recipient thereof solely
5 for the purposes of this litigation and not for any business or competitive purposes or
6 used in any other legal proceeding, except as permitted by order of the Court or as agreed
7 by the parties. It shall be the duty of each party and each individual having notice of this
8 Protective Order to comply with this Protective Order from the time of such notice.
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10 13. All deposition testimony shall be treated as containing Confidential
11 Information and subject to this Protective Order until a time thirty (30) calendar days
12 after the official transcript of such testimony is received. In the event that a party wishes
13 testimony or information disclosed at a deposition to be treated as Confidential
14 Information thereafter, that party shall designate such testimony or information as
15 Confidential Information by notifying the other party in writing, within thirty (30)
16 calendar days of receipt of the official transcript of the deposition, of the specific pages
17 and lines of the transcript which contain Confidential Information. Documents and
18 things already designated as Confidential Information which are used as exhibits shall
19 remain as such. If during a Court proceeding Confidential Information is likely to be
20 revealed, any party may request that the proceeding be held in camera. If such request is
21 granted by the Court, the transcript of such proceedings shall be treated as a deposition
22 transcript for the purposes of this Protective Order.
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25 **Miscellaneous**

26 14. This Protective Order is intended to provide a mechanism for handling the
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1 disclosure or production of Confidential Information to which there is no objection other
2 than confidentiality. Neither the agreement of the parties with respect to Confidential
3 Information, nor the designation of any information, document, or the like as
4 Confidential Information, nor the failure to make such designation shall constitute
5 evidence with respect to any issue on the merits in this action. Each party reserves the
6 right to object to any disclosure of information or production of any documents it deems
7 to contain Confidential Information on any other ground it may deem appropriate, and
8 any party may move for relief from, or general or particular modification of, the
9 mechanism herein set forth or the application of this Protective Order in any particular
10 circumstance.
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12 15. This Protective Order may be amended with respect to (a) specific
13 documents or items of Confidential Information or (b) persons to whom Confidential
14 Information may be disclosed, by Court order or by written agreement of the parties
15 hereto. This Protective Order shall remain in force and effect indefinitely until modified,
16 superseded, or terminated by order of this Court.
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18 16. Within sixty (60) days after the final termination of this action (including
19 all appeals), all documents, objects, and other materials produced as or designated as
20 Confidential Information, including extracts or summaries thereof, and all reproductions
21 thereof, including but not limited to that given to experts and inside counsel, shall be
22 returned to the designating party or shall be destroyed, at the option of counsel in
23 possession of such copies. If the materials are destroyed, counsel responsible for the
24 destruction shall within fifteen (15) calendar days of such destruction certify to counsel
25 for the designating party that destruction has taken place. However, outside counsel for
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1 each party may retain (a) one copy or sample of all material designated Confidential
2 Information for reference in the event of disputes over the use or disclosure of such
3 material, (b) documents, things, copies, and samples to the extent they include or reflect
4 receiving attorney's work product, and (c) one copy of pleadings or other papers filed
5 with the Court or served in the course of the litigation, the depositions, the deposition
6 exhibits, and the trial record.

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8 Nothing may be filed under seal, or removed from Court records, except by order
9 of the Court on cause shown.

10 17. No party or person shall disclose or cause to be disclosed to anyone not
11 specified in Paragraph 10 or Paragraph 21 as being entitled to receive it, any information
12 designated as Confidential Information under this Protective Order without prior written
13 consent of the designating party or an order of this Court. If the receiving party learns
14 that Confidential Information produced to it is disclosed to any person other than in the
15 manner authorized by this Protective Order, the receiving party learning of the disclosure
16 must immediately inform the designating party of all pertinent facts relating to such
17 disclosure and shall make every effort to prevent disclosure by each unauthorized person
18 who received such information.

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20 18. No person designated in accordance with Paragraph 10(b), (c), or (e) shall
21 have access to Confidential Information without first signing a Declaration of
22 Compliance with the Protective Order (in the form attached as Exhibit 1 hereto). A file
23 of all such original written Declarations shall be maintained by counsel for the party
24 obtaining them, and copies of declarations signed by persons designated in accordance
25 with Paragraph 10(b) or (c) shall be provided promptly to opposing counsel. Copies of
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1 declarations signed by persons designated in accordance with Paragraph 10(e) shall not
2 be provided to opposing counsel, but the names of such persons shall be disclosed to
3 opposing counsel.

4 19. Nothing herein shall prevent any party or non-party from seeking
5 additional relief from the Court not specified in this Protective Order, or from applying to
6 the Court for further or additional Protective Orders.

7 20. Nothing contained in this Protective Order shall be construed to restrain a
8 party or third party from disclosing its own Confidential Information as it deems
9 appropriate. Nothing contained in this Protective Order shall be construed to require
10 production of any Confidential Information deemed by counsel for the party or third
11 party possessing such material to be privileged or otherwise immune from discovery.
12 This shall not preclude any party from moving the Court for an order compelling
13 production or disclosure of such material.
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15 21. Nothing contained in this Protective Order shall be construed to limit any
16 party's rights (a) to use, in taking depositions of a party, its current or former employees,
17 or its experts or in briefs or at trial or in any proceeding in this litigation, any Confidential
18 Information, or (b) to disclose Confidential Information to any witness at a deposition or
19 at trial who either wrote (in whole or in part), received, or lawfully has or had access to
20 such information. In addition, a witness may be shown any document that contains or
21 reveals Confidential Information if the witness is a present officer, director, or current or
22 former employee of the producing party. However, any Confidential Information so used
23 shall not lose its confidential status through such use and its confidentiality shall be
24 protected in conformance with this Protective Order.
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1 22. If counsel believes that any question or questions that will be put to a
2 witness at deposition or at trial in this action will disclose material designated
3 Confidential Information, or that answers to any question or questions will require such
4 disclosure, or if material designated Confidential Information will be used as an exhibit at
5 such a deposition, counsel shall advise opposing counsel of same, and the deposition (or
6 confidential portions thereof), shall be conducted only in the presence of persons entitled
7 under the terms of this Protective Order access to Confidential Information.
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9 23. Nothing herein shall prevent a receiving party from contending (for the
10 purposes of securing an order so providing from the Court) that any or all Confidential
11 Information is not confidential or otherwise not entitled to protection. Any receiving
12 party may at any time request that the designating party cancel or change the Confidential
13 Information designation with respect to any document, object, or information. Such
14 request shall be written, shall be served on counsel for the designating party, and shall
15 particularly identify the designated Confidential Information that the receiving party
16 contends is not confidential and the reasons supporting its contention. If the designating
17 party does not agree to remove or change the Confidential Information designation, then
18 the party contending that such documents or information are not confidential may file a
19 motion to be relieved from the restrictions of this Protective Order with respect to the
20 document or information in question, and the designating party shall have the burden of
21 proving that its designation was appropriate. Production of documents and things for
22 purpose of inspection and copying shall not constitute a waiver of confidentiality as to
23 such documents or any other information.
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26 24. The restrictions and obligations set forth herein relating to material
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1 designated as Confidential Information shall not apply to any information which: (a) the
2 parties (and, if another person produced Confidential Information, such person) agree, or
3 the Court rules, is already public knowledge; (b) the parties (and any respective
4 producing person) agree, or the Court rules, has become public knowledge other than as a
5 result of disclosure by a receiving party, its employees, or agents in violation of this
6 Protective Order; (c) has come or shall come into a receiving party's legitimate
7 possession independently of the producing party; or (d) has been independently
8 developed by or for the party without use of, or reference to, the other party's
9 Confidential Information, which shall remain confidential.
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11 25. The parties agree that they will not request and are not under any
12 obligation to preserve or produce any correspondence or other communication with any
13 retained testifying experts, notes of any oral communication or written correspondence
14 with any retained testifying experts, notes taken by any retained testifying expert, or any
15 correspondence or other communication between the testifying expert and his or her
16 clerical or support staff unless such materials were relied upon by said testifying experts
17 in forming their opinions. Nor will the parties request nor are they under any obligation
18 to preserve or produce any drafts of any reports of any testifying expert.
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20 26. This Protective Order shall continue in effect after termination of this
21 action and continue to be binding upon all persons to whom Confidential Information is
22 disclosed hereunder.
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24 27. For any notice required under this Protective Order, notice received after
25 the close of business (6:00 p.m. Eastern time) shall be deemed received on the following
26 working day.
27

IT IS HEREBY ORDERED:



~~XXXXXXXXXXXXXXXXXXXX~~
~~The Honorable Gloria M. Navarro~~
~~UNITED STATES DISTRICT JUDGE~~
DATE: OCT. 26, 2010

/s/ Sundeep K. Addy

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EXHIBIT 1

**UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA**

BAYER SCHERING PHARMA AG &
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LUPIN LIMITED and LUPIN
PHARMACEUTICALS, INC.,

Defendants.

Civil Case No. 2:10-cv-0166-GMN-RJJ

DECLARATION OF COMPLIANCE

I, the undersigned, hereby acknowledge that I have read the Protective Order entered in this action, understand the terms thereof, agree to be bound by such terms, and agree to be subject to the jurisdiction of said Court in all matters relating to said Protective Order. I acknowledge that I will treat all information designated as "Confidential" strictly in accordance with the terms and conditions of this Protective Order and that I understand that any unauthorized use of such material that I receive may constitute contempt of court.

DATED: _____

Signature

Address: _____

Print Name